

MEMORANDUM

DATE: October 21, 1999

TO: Tom Bell, Mohandas Bhat, Frank Hawkins, Ruth Neta, Joe Weiss, and Libby White

FROM: Barrett Fountos *BS*

SUBJECT: Summary of the October 20, 1999 Meeting of the National Cancer Institute (NCI) Chernobyl Leukemia Working Group

The NCI Chernobyl Leukemia Working Group convened at the Bethesda Marriott Hotel to review the Phase I report of the Study of Leukemia, Lymphoma, and Related Disorders in Ukrainian Clean-up Workers Following the Chernobyl Accident and discuss possible options for Phase II.

The meeting was chaired by Dr. Gilbert Beebe and was attended by NCI staff Dr. Andre Bouville, Dr. Alina Brenner, Dr. Charles Land, Dr. Jay Lubin, Dr. Nicholas Luckyanov, Dr. Ian Magrath, Ms. Kathleen Stine, Dr. Terry Thomas, and Dr. Shelia Zahm, NCI consultants Dr. John Boice, Dr. Stuart Finch, Dr. Geoffrey Howe, Dr. Ronald Jensen, and Dr. Gayle Littlefield, Dr. Margot Tirmarche, Commissariat a L'Energie Atomique, Dr. Schlomo Yaniv, Nuclear Regulatory Commission, and Mr. Barrett Fountos, DOE.

Dr. Beebe presented a review of Phase I objectives, summarized the history of Phase I, and discussed the goal of the meeting, i.e., to recommend a path forward to NCI. Dr. Bouville discussed progress and problems in Phase I related to dosimetry; Dr. Finch discussed case ascertainment and whether to include lymphoma and molecular biology studies in Phase II; Dr. Boice discussed existing evidence of a real excess of leukemia from other studies; and Dr. Howe presented revised power calculations and the scientific promise of a Phase II study in the absence of a real observed effect. The group was pleased with the work performed in Phase I.

The group considered various options, including whether to repeat Phase I, conduct Phase II as in the protocol, conduct a modified Phase II study, or discontinue the project altogether. The group's major recommendation was to conduct a modified Phase II study with: 1) a focus on leukemia and multiple myeloma; 2) a change epidemiologic design from case-cohort to case-control; 3) a deletion of biodosimetry as a routine dosimetric method and emphasis on physical methods, especially electron paramagnetic resonance (EPR); and 4) a deletion of tissue collection and storage.

Dr. Howe defined a case as any male listed on the Ukrainian State Chernobyl Registry who was first employed as a clean-up worker between 1986 and 1990, who resides within the oblasts included in the study, and who was diagnosed with leukemia. Controls will be randomly chosen from the cohort based on residence in the study oblast and will be matched to cases on oblast and

age. The three dose groups are defined as low (< 0.25 Gy), medium (0.25 to 0.5 Gy), and high (> 0.5 Gy). Further work is needed to minimize the current uncertainty of dose estimates.

A draft report of the Phase I study, revised power calculations, and scientific rationale for the Phase II study are available in my office.

**National Cancer Institute
Division of Cancer Epidemiology and Genetics
NCI Chernobyl Leukemia Working Group**

Evaluation of Phase I and Recommendation as to Phase II

**Bethesda Marriott Hotel, 19 October, 1999
8:30 AM - 5:00 PM**

AGENDA

7:30 - 8:30 AM

Continental Breakfast

8:30 - 8:45 AM

**I. Review of Phase I Objectives (Beebe)
History of Phase I
Charge to Working Group**

II. Progress and Problems with Phase I

8:45 - 10:30 AM

**A. Dosimetry (Bouville)
Review of Phase I Report**

10:30 - 10:45 AM

Break

10:45 - 11:00 AM

**Proposal for Making Dose
Estimates For Retrospective
Cases and Controls**

11:00 AM - 12:00 PM

**B. Hematology (Finch)
Review of Phase I Report
Ascertainment of Retrospective
Cases
Inclusion of Lymphoma and
Molecular Studies in Any
Phase II Study
Inclusion of "Other Hematologic
Disorders" In Any Phase II Study**

12:00 - 1:00 PM

**C. Epidemiology (Beebe, Howe)
Review of Phase I Report**

1:00 - 2:00 PM

Lunch

2:00 - 3:00 PM	III. Consideration for Phase II Existing Evidence of Real Excess of Leukemia (Boice) New Power Calculations for Phase II (Howe)
3:00 - 4:00 PM	Scientific Promise of Phase II Study in (Howe) Absence of Real Effect
4:00 - 5:00 PM	IV. Recommendation for the Future: Phase II in Some Form, Yes or No General Discussion Recommendation of Working Group Members Expected Administrative Actions Following the Meeting
5:00 PM	V. Adjournment

NCI LEUKEMIA WORKING GROUP MEETING

OCTOBER 19, 1999

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